Complete Summary

GUIDELINE TITLE

Bacterial keratitis.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Bacterial keratitis. San Francisco (CA): American Academy of Ophthalmology (AAO); 2008. 27 p. [109 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cornea/External Disease Panel, Preferred Practice Patterns Committee. Bacterial keratitis. San Francisco (CA): American Academy of Ophthalmology (AAO); 2005. 20 p.

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all Preferred Practice Patterns are current, each is valid for 5 years from the "approved by" date unless superseded by a revision.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008 – Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bacterial keratitis, including the following:

- Corneal ulcer
- Corneal ulcer, unspecified
- Marginal corneal ulcer
- Ring corneal ulcer
- Central corneal ulcer
- Hypopyon ulcer
- Perforated corneal ulcer
- Corneal abscess
- Corneal infiltrate

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Ophthalmology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To minimize visual loss, relieve pain, eliminate the infectious agent, and minimize structural damage to the cornea by addressing the following goals:

- Recognize and reduce risk factors that predispose patients to bacterial infection of the cornea
- Establish the diagnosis of bacterial keratitis, differentiating it from other causes of keratitis
- Utilize appropriate diagnostic tests

- Select appropriate therapy
- Relieve pain
- Establish appropriate follow-up
- Prevent complications, such as medication toxicity, intraocular infection, cataract, corneal perforation, and loss of vision
- Educate patients and their families about treatment and ways to reduce risk factors in the future

TARGET POPULATION

Individuals of all ages who present with symptoms and signs suggestive of bacterial keratitis such as pain, redness, blurred vision, discharge, corneal infiltrates, ulcerations, and anterior chamber inflammation

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Medical and ocular history
2. Eye examination
    - Visual acuity
    - External examination
    - Slit-lamp biomicroscopy
3. Diagnostic tests
    - Cultures and smears
    - Corneal biopsy

Treatment/Management

1. Antibiotics (topical drops and ointments, subconjunctival, systemic)
2. Topical corticosteroids
3. Patient and care provider education
4. Follow-up
5. Referral to specialist for visual rehabilitation, if indicated

MAJOR OUTCOMES CONSIDERED

- Rate of disease progression
- Effectiveness of treatments
    - Resolution of corneal inflammation, infection/infiltrate
    - Reduction of pain
    - Restoration of corneal integrity and visual function
    - Minimization of scarring and vascularization
- Adverse effects of treatments

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In the process of revising this document, a detailed literature search of PubMed and the Cochrane Library for articles in the English language was conducted in December 2007 on the subject of bacterial keratitis for the years 2005 to 2007.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ratings of Strength of Evidence

Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

Level II includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of bacterial keratitis were reviewed by the Cornea/External Disease Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of Importance to the Care Process

Level A, defined as most important
Level B, defined as moderately important
Level C, defined as relevant, but not critical

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2007).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Ratings of importance to the care process (A-C) and ratings of strength of evidence (I-III) are defined at the end of the "Major Recommendations" field.

Diagnosis

History

- Ocular symptoms [A:III]
- Contact lens history (Dart, 1988; Schein & Poggio, 1990) [A:II]
- Review of other ocular history [A:III]
- Review of other medical problems and systemic medications [A:III]
- Current and recently used ocular medications [A:III]

- Medication allergies [A:III]

Examination

Visual Acuity

In many cases, patient discomfort, tearing, and inflammation will compromise visual acuity. It is useful, however, to document baseline visual acuity and to ascertain that it is consistent with the anterior segment examination. [A:III]

External Examination

- General appearance of the patient including skin conditions [B:III]
- Facial examination [B:III]
- Eyelids and eyelid closure [A:III]
- Conjunctiva [A:III]
- Nasolacrimal apparatus [B:III]
- Corneal sensation [A:III]

Slit-Lamp Biomicroscopy

- Eyelid margins [A:III]
- Conjunctiva [A:III]
- Sclera [A:III]
- Cornea [A:III]
- Anterior chamber [A:III]
- Anterior vitreous [A:III]
- Contralateral eye for clues to etiology as well as possible similar pathology [A:III]

Diagnostic Tests

Cultures and Smears

Smears and cultures are indicated in cases that involve a corneal infiltrate that is large and extends to the middle to deep stroma; that are chronic in nature or unresponsive to broad spectrum antibiotic therapy; or that have atypical clinical features suggestive of fungal, amoebic, or mycobacterial keratitis (Wilhelmus et al., 1994; Forster, 1998). [A:III] The hypopyon that occurs in eyes with bacterial keratitis is usually sterile, and aqueous or vitreous taps should not be performed unless there is a high suspicion of microbial endophthalmitis, such as following an intraocular surgery, perforating trauma, or sepsis. [A:III] Before initiating antimicrobial therapy, cultures are indicated in sight-threatening or severe keratitis of suspected microbial origin. [A:III]

Corneal scrapings for culture should be inoculated directly onto appropriate culture media to maximize culture yield (Waxman et al., 1999). [A:III] If this is not feasible, specimens should be placed in transport media (Kaye et al., 2003; McLeod et al., 2005). [A:III] In either case, cultures should be immediately incubated or taken promptly to the laboratory. [A:III]

Treatment and Follow-Up

Topical antibiotic eye drops are capable of achieving high tissue levels and are the preferred method of treatment in most cases (Forster, 1998). [A:III] See Table 2 in the original guideline document for recommendations about antibiotic therapy. For central or severe keratitis (e.g., deep stromal involvement or an infiltrate larger than 2 mm with extensive suppuration), a loading dose (e.g., every 5 to 15 minutes for the first 1 to 3 hours), followed by frequent applications (e.g., every 30 minutes to 1 hour around the clock), is recommended. [A:III]

Systemic therapy is necessary in cases of gonococcal keratitis ("Sexually transmitted diseases," 2002; Centers for Disease Control and Prevention, 2007). [A:II]

Frequency of re-evaluation of the patient with bacterial keratitis depends on the extent of disease, but severe cases (e.g., deep stromal involvement or larger than 2 mm with extensive suppuration) initially should be followed at least daily until stabilization or clinical improvement is documented. [A:III]

In general, the initial therapeutic regimen should be modified when the eye shows a lack of improvement or stabilization within 48 hours. [A:III]

If there is a persistent epithelial defect and the infection is under control, adjunctive therapies to rehabilitate the surface should be instituted, [A:III] such as lubrication, antibiotic ointment, or tarsorrhaphy.

Coexisting risk factors, such as eyelid abnormalities, should be corrected for optimal results. [A:III]

Counseling/Referral

Patients and care providers should be educated about the destructive nature of bacterial keratitis and the need for strict adherence to the therapeutic regimen. [A:III] The possibility of permanent visual loss and need for future visual rehabilitation should be discussed. [A:III] Patients who wear contact lenses should be educated about the increased risk of infection associated with contact lens wear, overnight wear, and the importance of adherence to techniques that promote contact lens hygiene (Larkin, Kilvington, & Easty, 1990; Poggio et al., 1989; Mondino et al., 1986; Stehr-Green et al., 1987). [A:II]

Visual rehabilitation restores functional ability (Stelmack et al., 2008), and patients with substantial visual impairment should be referred for vision rehabilitation and social services if they are not candidates for surgery (American Academy of Ophthalmology Vision Rehabilitation Panel, 2007). [A:III] More information on vision rehabilitation, including materials for patients, is available at http://www.aao.org/smartsight.

Definitions:

Ratings of Importance to Care Process

Level A, defined as most important
Level B, defined as moderately important
Level C, defined as relevant, but not critical

Ratings of Strength of Evidence

Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

Level II includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for most recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and appropriate management of bacterial keratitis

POTENTIAL HARMS

- Although there have been some concerns of increased risk of corneal perforation with *fluoroquinolones* in the treatment of severe bacterial keratitis

compared with traditional fortified topical antibiotics (cefazolin and tobramycin), these reports are retrospective, not from randomized controlled trials, and will need confirmation in future studies.
- *Collagen shields and soft contact lenses* soaked in antibiotics can become displaced or lost, leading to unrecognized interruption of drug delivery.
- Potential disadvantages of *topical corticosteroid therapy* include recrudescence of infection, local immunosuppression, inhibition of collagen synthesis predisposing to corneal melting, and increased intraocular pressure.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- **Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual**. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these *Preferred Practice Patterns* will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.
- **The Preferred Practice Pattern guidelines are not medical standards to be adhered to in all individual situations**. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.
- References to certain drugs, instruments, and other products are made for illustrative purposes only and are not intended to constitute an endorsement of such. Such material may include information on applications that are not considered community standard, that reflect indications not included in approved Food and Drug Administration (FDA) labeling, or that are approved for use only in restricted research settings. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use, and to use them with appropriate patient consent in compliance with applicable law.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Bacterial keratitis. San Francisco (CA): American Academy of Ophthalmology (AAO); 2008. 27 p. [109 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Sep (revised 2008 Sep)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology

GUIDELINE COMMITTEE

Cornea/External Disease Panel; Preferred Practice Patterns Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Cornea/External Disease Panel: Christopher J. Rapuano, MD, *Chair*; Robert S. Feder, MD; Matthew R. Jones, MD; Francis S. Mah, MD; Ayman

Naseri, MD; Audrey R. Talley-Rostov, MD; Andrew J. Velazquez, MD; Jayne S. Weiss, MD; David C. Musch, PhD, MPH, Methodologist

Members of the Preferred Practice Patterns Committee: Sid Mandelbaum, MD, *Chair*; Emily Y. Chew, MD; Linda M. Christmann, MD; Douglas E. Gaasterland, MD; Stephen D. McLeod, MD; Samuel Masket, MD; Christopher J. Rapuano, MD; Donald S. Fong, MD, MPH, Methodologist

Academy Staff: Flora C. Lum, MD; Nancy Collins, RN, MPH; Doris Mizuiri

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

These panel and committee members have disclosed the following financial relationships occurring from January 2007 to October 2008:

Robert S. Feder, MD: Alcon Laboratories, Inc. – Lecture fees

Donald S. Fong, MD, MPH: Merck – Consultant/Advisor

Douglas E. Gaasterland, MD: Inspire Pharmaceuticals – Consultant/Advisor; IRIDEX – Consultant/Advisor, Equity owner, Patents/Royalty

Francis S. Mah, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Lecture fees, Grant support; Allergan, Inc. – Consultant/Advisor, Lecture fees, Grant support; BD Medical - Ophthalmic Systems – Lecture fees; InSite Vision, Inc. – Consultant/Advisor, Lecture fees, Grant support; Inspire Pharmaceuticals, Inc. – Consultant/Advisor, Lecture fees, Grant support; Ista Pharmaceuticals – Consultant/Advisor, Lecture fees, Grant support; Mpex, Inc. – Consultant/Advisor, Grant support; Polymedix, Inc. – Consultant/Advisor, Grant support; Xoma, Inc. – Consultant/Advisor, Grant support

Samuel Masket, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Lecture fees, Grant support; Allergan, Inc. – Lecture fees; Bausch & Lomb, Inc. – Lecture fees; Omeros Pharmaceuticals, Inc. – Consultant/Advisor; Othera Pharmaceuticals, Inc. – Consultant/Advisor; PowerVision – Consultant/Advisor; Visiogen, Inc. – Consultant/Advisor

Stephen D. McLeod, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Grant support; InSite Vision, Inc. – Consultant/Advisor, Visiogen, Inc. – Consultant/Advisor, Equity owner, Grant support

David C. Musch, PhD, MPH: Acuity Pharmaceuticals – Consultant/Advisor; AqueSys, Inc. – Consultant/Advisor; Bausch & Lomb, Inc. – Consultant/Advisor; Glaukos Corp. – Consultant/Advisor; IRIDEX – Consultant/Advisor; MacuSight, Inc. – Consultant/Advisor; Midwest EyeBanks – Grant support; National Eye Institute – Grant support; NeoVista, Inc. – Consultant/Advisor; Neurotech USA, Inc. – Consultant/Advisor; OPKO Health, Inc. – Consultant/Advisor; XTL Biopharmaceuticals – Consultant/Advisor

Ayman Naseri, MD: QLT Phototherapeutics, Inc. – Equity owner; SurModics, Inc. – Equity owner

Christopher J. Rapuano, MD: Alcon Laboratories, Inc. – Lecture fees; Allergan, Inc. – Consultant/Advisor, Lecture fees; Inspire Pharmaceuticals – Lecture fees; Ista Pharmaceuticals – Lecture fees; Rapid Pathogen Screening – Equity/owner; Ziemer Ophthalmic Systems AG – Consultant/Advisor

Audrey R. Talley-Rostov, MD: Addition Technology – Consultant/Advisor, Lecture fees; Advanced Medical Optics – Consultant/Advisor, Lecture fees; Allergan, Inc. – Consultant/Advisor, Lecture fees; Visiogen, Inc. – Consultant/Advisor

Jayne S. Weiss, MD: Alcon Laboratories, Inc. – Lecture fees

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cornea/External Disease Panel, Preferred Practice Patterns Committee. Bacterial keratitis. San Francisco (CA): American Academy of Ophthalmology (AAO); 2005. 20 p.

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all Preferred Practice Patterns are current, each is valid for 5 years from the "approved by" date unless superseded by a revision.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2008 Nov. 22 p.

Electronic copies: Available in Portable Document Format (PDF) or Personal Digital Assistant (PDA) format from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 1, 1998. The information was verified by the guideline developer on January 11, 1999. The summary was updated by ECRI on January 29, 2001. The updated information was verified by the guideline developer on March 12, 2001. This NGC summary was updated by ECRI on January 6, 2006. The updated information was verified by the guideline developer on February 9, 2006. This summary was updated by ECRI Institute on April 22, 2009. The updated information was verified by the guideline developer on May 15, 2009.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 6/8/2009